GUIDANCE DOCUMENT FOR APPLICATION FOR REGISTRATION FOR POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS (APHIS/CDC FORM 1)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2008

INTRODUCTION

The U.S. Departments of Health and Human Services (HHS) and Agriculture (USDA) published final rules (7 CFR 331, 9 CFR 121, and 42 CFR 73), which implement the provisions of the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (Public Law 107-188) setting forth the requirements for possession, use, and transfer of select agents and toxins. The select agents and toxins identified in the final rules have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the HHS Secretary and to the Animal and Plant Health Inspection Service (APHIS) by the USDA Secretary. In order to minimize the reporting burden to the public, APHIS and CDC have developed a common reporting form for this data collection.

Unless exempted from the requirements set forth in 7 CFR 331, and 9 CFR 121, and 42 CFR 73, an individual or entity shall not possess, use, or transfer any select agent or toxin without a certificate of registration issued by APHIS or CDC. To apply for a certificate of registration, an individual or entity must submit the information requested in the registration application package (APHIS/CDC Form 1) to APHIS or CDC based on the type of select agent or toxin they may possess, use, or transfer. For HHS agents, the Responsible Official (RO) should submit this form to CDC (telephone: 404-498-2255, facsimile: 404-498-2265, or e-mail: lrsat@cdc.gov). For USDA agents, the RO should submit this form to APHIS (telephone: 301-734-5960, facsimile: 301-734-3652, e-mail: Agricultural.Select.Agent.Program@aphis.usda.gov). For HHS/USDA overlap agents, the RO may submit this form to APHIS or CDC, but not both. A listing of HHS select agents and toxins is available at http://www.cdc.gov/od/sap. A listing of USDA select agents and toxins is available at http://www.aphis.usda.gov/programs/ag_selectagent/index.html. Before you complete this application, please review the exemption and exclusion requirements set forth in 7 CFR 331, and 9 CFR 121, and 42 CFR 73 to determine whether your entity is required to register.

The entity should also perform a facility risk assessment (see 7 CFR 331.11-12, 9 CFR 121.11-12, and 42 CFR 73.11-12) that is based on the requirements for handling that agent to ensure that the facility meets those requirements. All entities using select agents and toxins should base their facility risk assessments on the applicable sections of the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), *NIH Guidelines for Research Involving Recombinant DNA* (*NIH Guidelines*), 29 CFR 1910.1450, or other required assessment materials. If information supplied in the application package indicates that the entity is properly equipped and capable of handling select agents and toxins, APHIS or CDC may issue a registration certificate to the entity. The registration is valid for a period up to three years. All entities will be subject to inspection during the three-year registration period.

If an entity's application fails to document that the entity is properly equipped and capable of work with select agents and toxins, or if the application is incomplete, the entity will not be registered. APHIS or CDC will inform the entity of problems with the application by contacting the designated RO. Upon resolution of the problem, the entity may again seek registration. Allow at least 8 weeks for processing. Submission of an incomplete application will result in a significant delay in processing the application. Currently, there is no fee for registration for select agents and toxins.

PURPOSE

The purpose of this form is to provide a method for entities to register to possess, use, or transfer select agents and toxins as described in 7 CFR 331.7, 9 CFR 121.7, and 42 CFR 73.7. The information requested in this form includes: facility information; a list of select agents or toxins to be possessed, used, or transferred by the entity; a list of individual who will have access to select agents and toxins; characterization of the select agents and toxins and additional laboratory information.

INSTRUCTIONS

(A) Designating a RO and alternate RO

The entity is required by the regulations to assign a RO to assume responsibility for providing application information to APHIS or CDC. The RO must have the authority and responsibility to act on behalf of the entity, ensure compliance with the requirements of 7 CFR 331, 9 CFR 121, and 42 CFR 73, and must be approved based on a security risk assessment by the Attorney General (Public Act 212(e)(3)). The purpose of the RO is to provide an established point of contact for the entity if APHIS or CDC has questions concerning the application or other matters related to the entity registration. The RO should consult with others (e.g., engineering support services, principal investigators, biosafety officers) as necessary to obtain the information required for this application.

An entity may also designate an alternate RO in cases where extended absences or other circumstances warrant acting for the RO in his or her absence. The alternate RO must meet all of the qualifications for a RO. We recommend that the RO and alternate RO

are biosafety officers or senior management officials of the entity, or both. Although we understand that some entities have limited staff, we recommend that the RO not be an individual actually using, working with, or transferring or receiving the select agents and toxins to minimize potential conflicts of interest.

To designate a different RO or an alternate RO, the current RO must mail or fax to the appropriate agency a signed statement on official entity facility letterhead requesting such changes. In addition, the new RO or alternate RO must submit completed Sections 1 and 2.

In the event that an entity loses the services of its Responsible Official, an entity may continue to possess or use select agents or toxins only if it appoints as the Responsible Official another individual who has been approved by the APHIS Administrator or HHS Secretary following a security risk assessment by the Attorney General and who meets the requirements of this part. The owner of the entity must mail or fax to the appropriate agency a signed statement on official entity facility letterhead requesting such changes. In addition, the new RO or alternate RO must submit Sections 1 and 2.

(B) Completing Application

1. Submission of an incomplete or illegible application will result in a significant delay in processing the application.
2. Section 1 – Entity Information
   a. Complete section 1 regarding entity, RO, and alternate RO information.
   b. If more than one alternate RO has been identified, additional sections 1C and 2 should be completed, as appropriate.
   c. If the entity was previously registered with APHIS or CDC, section 1D should be completed.
3. Section 2 – Certification and Signature form. This section must be completed and signed by the RO and all alternate RO(s) for the institution.
4. Section 3 – Select Agents and Toxins, Possessed, Used, or Transferred by Entity. Complete section to indicate each select agent or toxin which is currently in possession, use or in storage at the entity, or those agents that are anticipated in the near future (e.g., within 6 months).
5. Section 4A – Biosafety and Laboratory Information on Select Agents and Toxins.
   a. The following information must be listed on a separate line for each laboratory safety level: the select agent(s) or toxin(s); the type of work with each select agent or toxin (e.g., viable, genomic material, recombinant DNA, use in animals, or large scale), the building and room number(s) where select agent(s) or toxin(s) will be used and stored for each Principal Investigator (or Chief Scientist).
   b. The facility risk assessment based on the requirements for the type of activities conducted with each select agent and toxin in each of the rooms should be listed in the "Laboratory Safety Level" column.

Example 1. An entity needs to register one principal investigator (e.g., Dr. Jane Doe will be working with viable *Bacillus anthracis* in Bldg A, Room 2 at BSL-2; large scale production of *Bacillus anthracis* in Bldg A, Room 5 at BSL3; and *Bacillus anthracis* in mice in Bldg B, Room 200 at ABSL2). Storage of the select agents will be in the same locations where the work will be conducted.

EXAMPLE 1												
Select agent/Toxin name	Viable	Genomic material	Recombinant DNA	Animal	Large Scale	Toxin	Laboratory Area		Storage Area		Laboratory Safety Level	Principal Investigator
							Bldg	Room	Bldg	Room		
Bacillus anthracis	X						A	2	A	2	BSL2	Dr. Jane Doe
Bacillus anthracis	X				X		A	5	A	5	BSL3	Dr. Jane Doe
Bacillus anthracis	X			X			B	200	B	200	ABSL2	Dr. Jane Doe

Example 2. An entity needs to register three principal investigators (e.g., Dr. John Smith will be working with recombinant Ebola in Bldg 15, Room 100 at NIHBL-4; Dr. Mary Johnson will be working with botulinum toxins in Bldg 3A, Room 1000 under 29 CFR 1910.1450 conditions; and Dr. Tony Small will be working with viable *Francisella tularensis* in Bldg 4, Room 300 at BSL3 and viable *Brucella melitensis* in the same room). Storage of the agents will be in the same locations where the work will be conducted.

EXAMPLE 2												
Select agent/Toxin name	Viable	Genomic material	Recombinant DNA	Animal	Large Scale	Toxin	Laboratory Area		Storage Area		Laboratory Safety Level	Principal Investigator
							Bldg	Room	Bldg	Room		
Ebola virus			X				15	100	15	100	NIHBL4	Dr. John Smith
Botulinum toxin						X	3A	1000	3A	1000	29 CFR	Dr. Mary Johnson
Francisella tularensis	X						4	300	4	300	BSL3	Dr. Tony Small
Brucella melitensis	X						4	300	4	300	BSL3	Dr. Tony Small

6. Section 4B – Authorized Personnel Working with Select Agents and Toxins. Complete this section by providing the information for the RO, alternate RO, owners of the entity, as well as *each* person who is authorized to have access to select agents and toxins at the entity.
   a. The name (including middle initial), the date of birth and address, (including zip code) for individuals listed on this table should be identical to that given on the FBI form (FD-961) submitted to the Federal Bureau of Investigation (FBI), Criminal Justice Information Services Division (CJIS) for each individual. The first and last name of each individual should correspond exactly to the information submitted to CJIS.
   b. The "Principal Investigator" (PI) field on Table 4B refers to the individual who is supervising all activities associated with select agents and toxins in the specified rooms. Therefore, the PI listed in Table 4B must be a PI listed on Table 4A. This column should be left blank only for the RO, ARO, PI, and owner/controller of the entity.
   c. Amending Section 4B:
      1) To request additions to Section 4B, submit an amended Section 4B with the individual's information added to the same agency that you filed your original application with (APHIS or CDC).
      2) To request deletions to Section 4B, submit the Section 4B with the individual's information lined through or removed (if removed, include a cover letter indicating which individual's information was removed) to the same agency that you filed your original application with (APHIS or CDC). If the individual's access to select agents or toxins is terminated by the entity, the RO must submit the reason for termination along with the amended Section 4B.
   d. Submitting security risk assessment (SRA) information to CJIS:
      1) Once the entity has submitted an amended Section 4B listing new persons requiring an SRA, the RO receives the individual's unique Department of Justice (DOJ) identifying number from APHIS or CDC and forwards to the individual to complete the SRA information (FD-961 form and fingerprint cards).
      2) The individual should complete the FD-961 form including their unique DOJ identifying number in block 15 and follows the FBI instructions (http://www.fbi.gov/hq/cjisd/takingfps.html) for submitting fingerprints. The FD-961 form and fingerprint cards should be mailed as one package directly to CJIS, not to APHIS or CDC. Specific guidance on the process is available at http://www.cdc.gov/od/sap, http://www.aphis.usda.gov/programs/ag_selectagent/index.html, or http://www.fbi.gov/terrorinfo/bioterrorfd961.htm.

Example 3. John Johnson will be working with viable *Bacillus anthracis* in Bldg A, Room 2 at BSL-2 in Dr. Jane Doe's laboratory. Although Dr. Jane Doe may not be his immediate supervisor, her name should be listed because she is responsible for the select agent in this laboratory.

Last Name	First Name	Middle Initial	Date of Birth	Home Address (No P.O. boxes)	Principal Investigator (PI's, RO's, ARO's, and owners leave this column blank)	Select Agent(s)/ Toxin(s)	Laboratory Building	Laboratory Room	Job Title
Doe	Jane	A.	1/1/61	123 Street City, ST 01234		*Bacillus anthracis*	A	2	Principal Investigator
Johnson	John	D.	1/2/60	456 Lane City, ST 01234	Doe	*Bacillus anthracis*	A	2	Laboratorian

7. Section 5 – Principal Investigator and Laboratory Information. Complete this section for *each* principal investigator and each laboratory at the entity. Complete only sections as appropriate for the select agents and toxins in use for each principal investigator. If statement does not apply to the laboratory, check "N/A" box (if box is not available, write "N/A" beside statement).

(C) Submitting application to APHIS or CDC

1. To apply for a certificate of registration that covers only HHS select agents or toxins, an entity must submit the application package to CDC.
2. To apply for a certificate of registration that covers only USDA select agents or toxins, an entity must submit the application package to APHIS.
3. To apply for a certificate of registration that does not cover only HHS select agents or toxins (i.e., covers at least one overlap select agent and toxin, or covers any combination of HHS select agents and toxins and USDA select agents and toxins), an entity must submit the application package to APHIS or CDC, but not both.

(D) Amending certification of registration

The RO or his or her alternate RO are also responsible for notifying APHIS or CDC of any changes to the registration, such as modifications to authorized laboratory personnel, changes in currently registered laboratories, additional new laboratories that require registration, or any other changes to the information provided in this application. Prior to any change, the RO must apply for an amendment to a certificate of registration by submitting the relevant page(s) of the registration application and forwarding it to APHIS or CDC for approval.

FACILITY RISK ASSESSMENTS AND SAFETY LEVELS: REQUIREMENTS FOR HANDLING SELECT AGENTS

All entities using select agents should base their facility risk assessments on the applicable sections of the *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), *NIH Guidelines for Research Involving Recombinant DNA* (*NIH Guidelines*), 29 CFR 1910.1450, or other required assessment materials.

- Laboratories working with viable select agent viruses, bacteria, or fungi should base their facility risk assessments on the BMBL. Use the BMBL to determine the appropriate Biosafety Level (BSL) for the various types of work to be conducted with each of the select agents.
- Laboratories working with recombinant DNA or regulated genetic elements should base their facility risk assessment on the *NIH Guidelines* to determine the recommended Biosafety Level (BSL) for the type of work to be conducted with each of the select agents. Institutions using recombinant DNA for large animal studies or in large scale production should base their facility risk assessments on the *NIH Guidelines*, as there are no corresponding sections in the BMBL.
- Laboratories working with select agent toxins should meet the requirements of 29 CFR 1910.1450, *Occupational Exposure to Hazardous Chemicals in Laboratories*. Additional guidance regarding toxin may be found in the BMBL. If the entity is also working with viable select agent toxin-producing organisms or recombinant DNA encoding for select agent toxins, the laboratory should base its facility risk assessments on the BMBL and *NIH Guidelines* in addition to 29 CFR 1910.1450.
- Distributors of toxins in which the toxins are only handled in sealed containers should meet the requirements of 29 CFR 1910.1200, *Hazard Communication*.

ADDITIONAL REFERENCE MATERIALS:

(1) *Biosafety in Microbiological and Biomedical Laboratories* (BMBL). The BMBL is available on the internet at http://www.cdc.gov/od/sap. An errata sheet for the most current edition of the BMBL is available at the internet website: http://www.cdc.gov/od/sap.

(2) *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines*). The *NIH Guidelines* are available at http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html.

(3) 29 CFR 1910.1450 - *Occupational Exposure to Hazardous Chemicals in the Laboratory.* Available on the Internet at http://www.osha.gov or from the U.S. Government Printing Office (phone 202-512-1800).

(4) 29 CFR 1200 - *Hazard Communication.* Available on the Internet at http://www.osha.gov or from the U.S. Government Printing Office (phone 202-512-1800).

(5) Additional information and clarification is available at http://www.cdc.gov/od/sap and http://www.aphis.usda.gov/programs/ag_selectagent/index.html.

OBTAINING EXTRA COPIES OF THIS FORM

Additional copies of this form are available on the APHIS website (http://www.aphis.usda.gov/programs/ag_selectagent/index.html) or the CDC website (http://www.cdc.gov/od/sap) or by contacting APHIS at (301) 734-5960 or CDC at (404) 498-2255.

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APPLICATION FOR REGISTRATION FOR POSSESSION, USE, AND TRANSFER OF SELECT AGENTS AND TOXINS (APHIS/CDC FORM 1)

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 12/31/2008

Read all instructions carefully before completing the application. Answer all items completely and type or print in ink. Failure to complete this application in detail will delay processing of your application. This report must be signed and submitted to either APHIS or CDC:

Animal and Plant Health Inspection Service
Agricultural Select Agent Program
4700 River Road Unit 2, Mailstop 22, Cubicle 1A07
Riverdale, MD 20737
FAX: 301-734-3652

Centers for Disease Control and Prevention
Division of Select Agents and Toxins
1600 Clifton Road NE, Mailstop E-79
Atlanta, GA 30333
FAX: 404-498-2265

SECTION 1 – ENTITY INFORMATION (TO BE COMPLETED BY ALL RO'S)

This application is: ☐ A new registration ☐ An amendment to an existing registration

SECTION 1A– ENTITY INFORMATION

Entity registration number (e.g., A00000000-0000): APHIS# CDC#			Date:
Legal name of entity:			
Address (NOT a post office box):	City:	State:	Zip Code:

Type of entity: ☐ Academic (Private) ☐ Academic (State) ☐ Commercial (Profit) ☐ Government (Federal) ☐ Government (State/Local) ☐ Private (Non-Profit)

SECTION 1B– RESPONSIBLE OFFICIAL INFORMATION

Name of Responsible Official:	Last Name:	First Name:	Middle Name:
Date of birth:	Title of Responsible Official (e.g., biosafety officer):		
Business Telephone:	Business FAX:	Business E-mail:	
Business Address (NOT a post office box):	City:	State:	Zip Code:

SECTION 1C – ALTERNATE RESPONSIBLE OFFICIAL INFORMATION

Name of Alternate Responsible Official:	Last Name:	First Name:	Middle Name:
Date of birth:	Title of Alternate Responsible Official (e.g., biosafety officer):		
Business Telephone:	Business FAX:	Business E-mail:	
Business Address (NOT a post office box):	City:	State:	Zip Code:
Name of Alternate Responsible Official:	Last Name:	First Name:	Middle Name:
Date of birth:	Title of Alternate Responsible Official (e.g., biosafety officer):		
Business Telephone:	Business FAX:	Business E-mail:	
Business Address (NOT a post office box):	City:	State:	Zip Code:

SECTION 1D – REGISTRATION HISTORY

Has this entity previously been registered with the Select Agent Program? ☐ Yes ☐ No
If yes, then provide Select Agent Program registration number and expiration date:

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SECTION 2 – CERTIFICATION AND SIGNATURE
(TO BE COMPLETED BY ALL RO'S AND ALTERNATE RO'S)

I hereby certify that I have been designated as the Responsible Official or the Alternate Responsible Official for the institution/organization listed above, that I am authorized to bind the institution/organization, and that the information supplied in this registration package is, to the best of my knowledge, accurate and truthful. The institution/organization listed above meets the requirements specified in 42 C.F.R. Part 73 and/or 7 C.F.R. Part 331 and/or 9 C.F.R. Part 121, is equipped and capable of safely and securely handling the agent(s), and will use or transfer these agents solely for purposes authorized by 42 C.F.R. Part 73 and/or 7 C.F.R. Part 331 and/or 9 C.F.R. Part 121.

I understand that submission of a false statement and/or failure to comply with the provisions of the applicable regulations (7 C.F.R. Part 331 and/or 9 C.F.R. Part 121 and/or 42 C.F.R. Part 73) may result in the immediate revocation of this entity's registration, a civil penalty of up to $500,000 for each violation, and a criminal penalty and/or imprisonment up to five years for each violation. (7 U.S.C. 8401; 18 U.S.C. 175, 175B, 1001, 3559, 3571; 42 U.S.C. 262a).

Responsible Official Signature	Date	Responsible Official Name (typed or printed)
Alternate Responsible Official Signature	Date	Alternate Responsible Official Name (typed or printed)
Alternate Responsible Official Signature	Date	Alternate Responsible Official Name (typed or printed)

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Date:_____

SECTION 3 – SELECT AGENTS AND TOXINS POSSESSED, USED, OR TRANSFERRED BY ENTITY
(TO BE COMPLETED BY ALL RO'S)

Indicate each select agent or toxin that your entity intends to register by placing an "X" in the box for each agent or toxin (check one or more as appropriate). Select agents or toxins that are exempt or excluded from registration should not be listed on this form. For information on completing this section, refer to page 2 of the guidance document.

HHS SELECT AGENTS AND TOXINS

- ☐ Abrin
- ☐ Cercopithecine herpesvirus 1 (Herpes B virus)
- ☐ *Coccidioides posadasii*
- ☐ Conotoxins
- ☐ Crimean-Congo haemorrhagic fever virus
- ☐ Diacetoxyscirpenol
- ☐ Ebola virus
- ☐ Lassa fever virus
- ☐ Marburg virus
- ☐ Monkeypox virus
- ☐ Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
- ☐ Ricin
- ☐ *Rickettsia prowazekii*
- ☐ *Rickettsia rickettsii*
- ☐ Saxitoxin
- ☐ Shiga-like ribosome inactivating proteins
- South American Haemorrhagic Fever viruses
  - ☐ Flexal
  - ☐ Guanarito
  - ☐ Junin
  - ☐ Machupo
  - ☐ Sabia
- ☐ Tetrodotoxin
- Tick-borne encephalitis complex (flavi) viruses
  - ☐ Central European Tick-borne encephalitis
  - ☐ Far Eastern Tick-borne encephalitis
  - ☐ Kyasanur Forest disease
  - ☐ Omsk Hemorrhagic Fever
  - ☐ Russian Spring and Summer encephalitis
- ☐ Variola major virus (Smallpox virus)
- ☐ Variola minor virus (Alastrim)
- ☐ *Yersinia pestis*

OVERLAP SELECT AGENTS AND TOXINS

- ☐ *Bacillus anthracis*
- ☐ Botulinum neurotoxins
- ☐ Botulinum neurotoxin producing species of *Clostridium*
- ☐ *Brucella abortus*
- ☐ *Brucella melitensis*
- ☐ *Brucella suis*
- ☐ *Burkholderia mallei* (formerly *Pseudomonas mallei*)
- ☐ *Burkholderia pseudomallei* (formerly *Pseudomonas pseudomallei*)
- ☐ *Clostridium perfringens* epsilon toxin
- ☐ *Coccidioides immitis*
- ☐ *Coxiella burnetii*
- ☐ Eastern Equine Encephalitis virus
- ☐ *Francisella tularensis*
- ☐ Hendra virus
- ☐ Nipah virus
- ☐ Rift Valley fever virus
- ☐ Shigatoxin
- ☐ Staphylococcal enterotoxins
- ☐ T-2 toxin
- ☐ Venezuelan Equine Encephalitis virus

USDA SELECT AGENTS AND TOXINS

- ☐ African horse sickness virus
- ☐ African swine fever virus
- ☐ Akabane virus
- ☐ Avian influenza virus (highly pathogenic)
- ☐ Bluetongue virus (Exotic)
- ☐ Bovine spongiform encephalopathy agent
- ☐ Camel pox virus
- ☐ Classical swine fever virus
- ☐ *Cowdria ruminantium* (Heartwater)
- ☐ Foot-and-mouth disease virus
- ☐ Goat pox virus
- ☐ Japanese encephalitis virus
- ☐ Lumpy skin disease virus
- ☐ Malignant catarrhal fever virus (Alcelaphine herpesvirus type 1)
- ☐ Menangle virus
- ☐ *Mycoplasma capricolum*/ M.F38/*M. mycoides Capri* (contagious caprine pleuropneumonia)
- ☐ *Mycoplasma mycoides mycoides* (contagious bovine pleuropneumonia)
- ☐ Newcastle disease virus (velogenic)
- ☐ Peste des petits ruminants virus
- ☐ Rinderpest virus
- ☐ Sheep pox virus
- ☐ Swine vesicular disease virus
- ☐ Vesicular stomatitis virus (Exotic)

USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS

- ☐ *Candidatus* Liberobacter africanus
- ☐ *Candidatus* Liberobacter asiaticus
- ☐ *Peronosclerospora philippinensis*
- ☐ *Ralstonia solanacearum* race 3, biovar 2
- ☐ *Schlerophthora rayssiae* var *zeae*
- ☐ *Synchytrium endobioticum*
- ☐ *Xanthomonas oryzae* pv. *oryzicola*
- ☐ *Xylella fastidiosa* (citrus variegated chlorosis strain)

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SECTION 4 – SELECT AGENT AND TOXIN INFORMATION
(TO BE COMPLETED BY ALL RO'S)

SECTION 4A. BIOSAFETY AND LABORATORY INFORMATION ON SELECT AGENTS AND TOXINS

Provide the following information on a **separate line** for each laboratory safety level: the select agent or toxin; the type of work with each select agent or toxin (e.g., viable, genomic material, recombinant DNA, use in animals, or large scale), the building and room number(s) where each select agent or toxin will be used and stored, and laboratory safety level for each Principal Investigator (or Chief Scientist). For entities only **storing** and not actively working with select agents or toxins, do not complete "laboratory area" column. For information on completing this section, refer to page 2 of the guidance document.

Dup Rows P.8 Dup Rows P.8-1 Dup Rows P.8-2 Dup Rows P.8-3

Select agent/Toxin name	Viable	Genomic Material	Recombinant DNA	Animal	Large Scale	Toxin	Laboratory Area		Storage Area		Laboratory Safety Level*	Principal Investigator	
							Bldg	Room	Bldg	Room			
	INDICATE WITH AN "X" FOR EACH SELECT AGENT/TOXIN AS APPROPRIATE												
	☐	☐	☐	☐	☐	☐							Dup Row
	☐	☐	☐	☐	☐	☐							Dup Row
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*Biosafety Level 2=BSL2
Biosafety Level 3=BSL3
Biosafety Level 4=BSL4

Animal Biosafety Level 2=ABSL2
Animal Biosafety Level 3=ABSL3
Animal Biosafety Level 4=ABSL4

rDNA BSL2=NIHBL2
rDNA BSL3=NIHBL3
rDNA BSL4=NIHBL4

rDNA Large Animal BSL2=NIH BL2N
rDNA Large Animal BSL3=NIH BL3N
rDNA Large Animal BSL4=NIH BL4N

rDNA Large Scale BSL2=NIH BL2-LS
rDNA Large Scale BSL3=NIH BL3-LS
rDNA Large Scale BSL4=NIH BL4-LS

Toxin= 29 CFR 1910.1450, 29 CFR 1910.1200 and BMBL

I certify that the select agents and toxins listed are categorized commensurate with the risk of the select agent or toxin and its intended use, and the biosafety and containment procedures are sufficient to contain the select agent or toxin.

Responsible Official/Alternate Responsible Official Signature:______________________________ Date: __________

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This application is: ☐ A new registration ☐ An amendment to an existing registration	Date
Legal name of entity:	Entity registration number (e.g., A00000000-0000): APHIS# CDC#

SECTION 4B – AUTHORIZED PERSONNEL WORKING WITH SELECT AGENTS AND TOXINS
(TO BE COMPLETED BY ALL RO'S)

Provide the following information for the Responsible Official (RO), Alternate Responsible Official (ARO), owners of the entity, as well as *each* person who is authorized to have access to select agents and toxins at the entity. If the person listed is identified to own or control the entity, indicate "Y" in the "Owner/Controller" column. The name (including middle initial) and the date of birth and address (including zip code) for individuals listed on this table should be identical to that given on the FD-961 Form submitted to CJIS for each individual. To request additions to or deletions from this list of individuals, submit this page to the agency that you filed your original application (APHIS or CDC). For information on completing this section, refer to page 3 of the guidance document.

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Last Name	First Name	Middle Initial	Date of Birth (mmddyr)	Home Address (No P.O. boxes)	Principal Investigator (PI's, RO's, ARO's, and owners leave this column blank)	Select Agent(s)/Toxin(s)	Laboratory Building	Laboratory Room	Job Title	Owner/ Controller (Y/N)	
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I certify that information and training on safety and security for working with select agents and toxins has been provided to the individuals listed above who will have access to select agents and toxins.

Responsible Official/Alternate Responsible Official Signature:_____ Date: _____

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